CAUTION:

IF YOU ARE USING A PUBLIC ACCESS COMPUTER, (I.E., PUBLIC LIBRARY, ETC.) BE CERTAIN YOU DRAG THIS FORM TO THE TRASH CAN AND EMPTY THE TRASH WHEN FINISHED.

THIS WILL PREVENT UNAUTHORIZED ACCESS TO PERSONAL INFORMATION SUCH AS YOUR NAME, HOME ADDRESS, AND SOCIAL SECURITY NUMBER.

Released 06/20/99. Submitted to but not yet approved by NIH Forms Officer.

OMB No. 0925-0137

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROTECTION OF HUMAN SUBJECTS ASSURANCE/CERTIFICATION/DECLARATION

☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION (previously undesignated)

☐ GRANT ☐ CONTRACT ☐ FELLOW ☐ OTHER

☐ New ☐ Competing continuation ☐ Noncompeting continuation ☐ Supplemental

APPLICATION IDENTIFICATION NO. *(if known)*

POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46--as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request form HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(see reverse side)*

4. HHS ASSURANCE STATUS

☐ This institution has an approved assurance of compliance on file with HHS which covers this activity.

_____ Assurance identification number _____ IRB identification number

☐ No assurance of compliance which applies to this activity has been established with HHS but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

☐ This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device *(see reverse side of this form).*

_____ Date of IRB review and approval. *(If approval is pending, write "pending". Followup certification is required.)*
(month/day/year)

☐ Full Board Review ☐ Expedited Review

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification *(form HHS 596)* will be submitted.

☐ Human subjects are involved but this activity qualifies for exemption under 46.101(b) in accordance with paragraph ____ *(insert paragraph number of exemption in 46.101(b), 1 through 5)*, but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO.	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL *(print or type)*	NAME AND TITLE OF OFFICIAL *(print or type)*
SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)*	SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)*

HHS 596 (Rev. 1/82)

(If additional space is needed, please use reverse side under "Notes.")

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(from front side)*
According to 45 CFR 46.121, if an application is made to HHS requiring certification and involving use of an investigational new drug or device, additic information is required. In addition, according to 21 CFR 312.1(a)(2), 30 days must elapse between date of receipt by FDA of Form FD-1571 and use of the drug, unless the 30 day delay period is waived by FDA.

3a. INVESTIGATIONAL NEW DRUG EXEMPTION (*if more than one is involved, list others below under NOTES):*

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER	NUMBER ISSUED

3b. INVESTIGATIONAL DEVICE EXEMPTION:

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (ii) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a non-significant risk device; and (2) the IRB has approved the study. *(Check applicable box.)*

☐ The IRB agrees with the sponsor that this device is a nonsignificant risk device.

OR

☐ The IDE application was submitted to FDA on *(date)* _____. Number issued _____

NOTES: